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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,123	04/24/2001	Shigeru Iida	001560-397	2738

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/02/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant's Name

09/830,123

Applicant(s)

IIDA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,23-30 and 47-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,11-22 and 31-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-8, 11-22 and 31-46, in Paper No. 10, is acknowledged. The traversal is on the ground(s) that Applicants are entitled to a unity of invention standard for determining restriction as the instant application was filed under § 371 and the instant invention has unity of invention, and because the cited prior art reference of Gaxiola et al. does not break the unity of invention because Gaxiola et al. do not teach or suggest the control of flower color. This is not found persuasive because a unity of invention standard for determining restriction was applied to the instant application. The instant invention lacks unity because the cited prior art reference of Gaxiola et al. does teach or suggest a gene encoding a protein that has an activity of regulating the pH of vacuoles in plant cells that would inherently control flower color, and because the prior art also explicitly teaches a gene encoding a protein that has an activity of regulating the pH of vacuoles in plant cells and that controls flower color (see Chuck et al. cited under 35 USC §102 *infra*), such that a gene encoding a protein that has an activity of regulating the pH of vacuoles in plant cells and that controls flower color does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Accordingly, claims 9-10, 23-30 and 47-51 are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed April 24, 2001, Paper No. 8, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8, 11-14, 16-18, 20-22, 32-34, 36-38, 40-42 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acids encoding a protein that has an activity of regulating the pH of vacuoles in plant cells, including a nucleic acid encoding an amino acid sequence modified by the addition or deletion of one or a plurality of amino acids and/or substitution with other amino acids in the amino acid sequence of SEQ ID NO:2, a nucleic acid encoding an amino acid sequence having 20% or more or 70% or more sequence identity with the amino acid sequence of SEQ ID NO:2, and a nucleic acid that hybridizes to a part or all of a nucleic acid encoding the amino acid sequence of SEQ ID NO:2.

The specification describes a Purple gene cDNA of SEQ ID NO:1 obtained from morning glory encoding the amino acid sequence set forth in SEQ ID NO:2 (sequence listing). The specification also describes the amino acid sequence set forth in SEQ ID NO:2 as having 29.3% identity with Nhxl, a Na⁺-H⁺ antiporter of yeast, and 73.4% sequence identity with AtNhxl, a Na⁺-H⁺ antiporter of *Arabidopsis* (page 14). The specification also describes a Na⁺-H⁺ antiporter function for the polypeptide of SEQ ID NO:2 (page 15). The specification does not describe the structure of any novel nucleotide sequence encoding a protein that has an activity of regulating the pH of vacuoles in plant cells having any amino acid sequence other than SEQ ID

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NO:2. The specification does not describe the structure of any nucleotide sequence encoding a protein that has an activity of regulating the pH of vacuoles in plant cells in which the amino acid sequence of SEQ ID NO:2 has been deleted, added to, or substituted. The specification does not describe the structure of any nucleotide sequence encoding a protein that has an activity of regulating the pH of vacuoles in plant cells which hybridizes to a nucleic acid encoding SEQ ID NO:2. The specification does not describe the structure of any novel nucleotide sequence encoding a protein that has an activity of regulating the pH of vacuoles in plant cells which has 20% or more or 70% or more sequence identity to SEQ ID NO:2.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed product, any method of using it would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement

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guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 1, 3-8, 11-14, 16-18, 20-22, 32-34, 36-38, 40-42 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding an amino acid sequence of SEQ ID NO:2 and methods of transforming plants and plant cells using said isolated nucleic acid, does not reasonably provide enablement for other isolated nucleic acids or methods of using other isolated nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to nucleic acids encoding a protein that has an activity of regulating the pH of vacuoles in plant cells, including a nucleic acid encoding the amino acid sequence of SEQ ID NO:2, a nucleic acid encoding an amino acid sequence modified by the addition or deletion of one or a plurality of amino acids and/or substitution with other amino acids in the amino acid sequence of SEQ ID NO:2, a nucleic acid encoding an amino acid sequence having 20% or more or 70% or more sequence identity with the amino acid sequence of SEQ ID NO:2, and a nucleic acid that hybridizes to a part or all of a nucleic acid encoding the amino acid sequence of SEQ ID NO:2. The claims are also drawn to vectors, host cells, plants and cut flowers comprising said nucleic acids, and to methods of regulating the pH of vacuoles and controlling the flower color of a plant by transforming a plant with said nucleic acids.

The specification discloses the cloning of the morning glory Purple gene the mutation of which results in purple rather than blue flowers (pages 12-14), and the isolation from morning

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glory of a Purple gene cDNA of SEQ ID NO:1 encoding the amino acid sequence set forth in SEQ ID NO:2 (page 14). The specification also discloses that the amino acid sequence set forth in SEQ ID NO:2 has 29.3% identity with Nhx1, a Na⁺-H⁺ antiporter of yeast, and 73.4% sequence identity with AtNhx1, a Na⁺-H⁺ antiporter of *Arabidopsis* (page 14). The specification discloses that the polypeptide of SEQ ID NO:2 has an Na⁺-H⁺ antiporter function as evidenced by the complementation of a yeast Nhx1 mutant (page 15). The specification does not disclose how to make specific deletions, additions or substitutions in SEQ ID NO:2 such that the encoded protein would retain an activity of regulating the pH of vacuoles in plant cells. The specification does not disclose the isolation of sequences that hybridize with a nucleic acid encoding SEQ ID NO:2 under stringent conditions and that encode a protein that has an activity of regulating the pH of vacuoles in plant cells. The specification does not disclose the isolation of sequences encoding proteins having an activity of regulating the pH of vacuoles in plant cells and that have 20% or more or 70% or more sequence identity to SEQ ID NO:2.

Guidance for making and using the claimed invention is necessary for enablement because it is unpredictable whether an amino acid sequence of SEQ ID NO:2 that has been deleted, added to, or substituted will encode a functional polypeptide. It is also unpredictable whether a sequence that hybridizes under stringent conditions to a part of or all of a nucleic acid encoding SEQ ID NO:2 or that encodes a polypeptide having 20% or more or 70% or more sequence identity to SEQ ID NO:2 will encode a functional polypeptide. A change in as few as one nucleotide in a base sequence, such as would occur by deletion, addition, substitution, hybridization or as a consequence of percent identity, can alter the amino acid sequence of the polypeptide it encodes, and a change in as few as one amino acid in a polypeptide can alter or eliminate its function. For example, Rhoads et al. (J. Biol. Chem., November 1998, Vol. 273, No.

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46, pages 30750-30756) teach that mutation of Cys-128 to Ala in an *Arabidopsis* alternative oxidase caused a pronounced overall increase in enzyme activity relative to the wild-type in the presence or absence of pyruvate (page 30753 Figure 3). Mutation of Cys-78 to Ala in the same *Arabidopsis* alternative oxidase resulted in a minimally active enzyme that showed no response to added pyruvate (page 30753 Figure 3).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which of the claimed nucleic acid sequences would encode a functional and therefore useful polypeptide.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 11-12, 18, 22, 30-38, 42 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6, and claims 18, 22, 30, 34, 38, 42 and 46 dependent thereon, is indefinite in the recitation of “a stringent condition”. It is unclear what conditions would yield the claimed nucleic acid, as those skilled in the art define stringency conditions differently. It is suggested that the claims be amended to recite specific hybridization conditions, if basis in the specification exists for same.

Claims 11-12 and 31-38 are indefinite in the recitation of “a progeny thereof having the same property as said plant”. There is insufficient antecedent basis for the limitation “same property” in the claims. It is also unclear which property of the plant the progeny exhibits, as a

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plant may exhibit many different properties, such as flower color, salt tolerance, disease resistance, etc.

Claims 12 and 35-38 are indefinite in the recitation of “or a progeny thereof”. It is unclear how one would obtain progeny from a cut flower.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a gene.

Claims 1-6, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “Isolated nucleic acid” or “Purified nucleic acid”. See MPEP 2105.

Claims 11-12 and 31-38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to progeny or a tissue of a plant into which a gene has been introduced, but the claims are not limited to progeny or a tissue that comprise the gene that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene

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introduced into the parent plant would only be transferred to half of the seeds of that plant. Also, introduction of a gene into a plant would not necessarily result in the introduction of that gene into all of the tissues of the plant. In addition, given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny or a tissue, it is unclear whether the claimed progeny or a tissue would be distinguishable from progeny or a tissue that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to recite that the progeny or a tissue comprise the isolated nucleic acid that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-8, 11-14, 16, 18, 20, 22, 32, 34, 36, 38, 40, 42, 44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Chuck et al. (US Patent 5,910,627 issued June 8, 1999).

The claims are drawn to nucleic acids encoding a protein that has an activity of regulating the pH of vacuoles in plant cells, including a nucleic acid encoding an amino acid sequence modified by the addition or deletion of one or a plurality of amino acids and/or substitution with other amino acids in the amino acid sequence of SEQ ID NO:2, and a nucleic acid that

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hybridizes to a part or all of a nucleic acid encoding the amino acid sequence of SEQ ID NO:2.

The claims are also drawn to vectors, host cells, plants and cut flowers comprising said nucleic acids, and to methods of regulating the pH of vacuoles and controlling the flower color of a plant by transforming a plant with said nucleic acids.

Chuck et al. teach nucleic acids encoding a petunia Ph protein that has an activity of regulating the pH of vacuoles in plant cells, and methods of regulating the pH of vacuoles and controlling the flower color of a plant by transforming a plant with said nucleic acids (column 13 line 62 through column 22 line 21, SEQ ID NOS: 3 and 4, columns 31-34 claims 1-21). While Chuck et al. do not explicitly teach how to make a nucleic acid encoding a protein modified by the addition or deletion of one or a plurality of amino acids and/or substitution with other amino acids in Applicant's amino acid sequence of SEQ ID NO:2, such a nucleic acid reads on the nucleic acid taught by Chuck et al. as such a nucleic acid would read on any nucleic acid encoding a protein having as few as one amino acid in common with Applicant's amino acid sequence of SEQ ID NO:2 and that encodes a protein that has an activity of regulating the pH of vacuoles in plant cells. Likewise, while Chuck et al. do not explicitly teach how to make a nucleic acid that hybridizes to a part or all of a nucleic acid encoding Applicant's amino acid sequence of SEQ ID NO:2, such a nucleic acid reads on the nucleic acid taught by Chuck et al. as such a nucleic acid would read on any nucleic acid that hybridizes to as few as one nucleotide in Applicant's nucleic acid and that encodes a protein that has an activity of regulating the pH of vacuoles in plant cells.

Claims 1, 3-8, 16-18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaxiola et al. (Proc. Natl. Acad. Sci. USA, Vol. 96, pages 1480-1485, February 1999, Applicant's IDS).

The claims are drawn to nucleic acids encoding a protein that has an activity of regulating the pH of vacuoles in plant cells, including a nucleic acid encoding an amino acid sequence modified by the addition or deletion of one or a plurality of amino acids and/or substitution with other amino acids in the amino acid sequence of SEQ ID NO:2, a nucleic acid encoding an amino acid sequence having 20% or more or 70% or more sequence identity with the amino acid sequence of SEQ ID NO:2, and a nucleic acid that hybridizes to a part or all of a nucleic acid encoding the amino acid sequence of SEQ ID NO:2. The claims are also drawn to vectors and host cells comprising said nucleic acids.

Gaxiola et al. teach a nucleic acid encoding AtNhx1, an Na⁺-H⁺ antiporter of *Arabidopsis* having 73.4% sequence identity with SEQ ID NO:2, as well as a vector and host cell comprising said nucleic acid (page 1481 column 2 first full paragraph, and specification page 14). The protein encoded by the nucleic acid taught by Gaxiola et al. would inherently have an activity of regulating the pH of vacuoles in plant cells, as the protein encoded by the nucleic acid disclosed by Applicant also exhibits an Na⁺-H⁺ antiporter function. The nucleic acid taught by Gaxiola encodes an amino acid sequence modified by the addition or deletion of one or a plurality of amino acids and/or substitution with other amino acids in the amino acid sequence of SEQ ID NO:2, as the protein encoded by the nucleic acid taught by Gaxiola has 73.4% sequence identity with SEQ ID NO:2. The nucleic acid taught by Gaxiola would hybridize to a part or all of a nucleic acid encoding the amino acid sequence of SEQ ID NO:2, as the protein encoded by the nucleic acid taught by Gaxiola has 73.4% sequence identity with SEQ ID NO:2.

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Remarks

No claim is allowed.

Claims 2, 15, 19, 31, 35, 39 and 43 are deemed free of the prior art due to the failure of the prior art to teach or suggest an isolated nucleic acid encoding an amino acid sequence of SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 26, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

